

### **REMARKS**

With entry of this Amendment, claims 13, 14, 16, and 17 are pending and under examination. Applicants have canceled claims 10-12 and 15 without prejudice or disclaimer of the subject matter of those claims and reserve the right to pursue the subject matter of these claims in a subsequent application. Applicants amended claim 13 to depend on claim 16 and to recite "treatment of xerostomia accompanying Sjögren's syndrome or of hyposalivation" and also amended claim 14 to depend on claim 17. Claims 16 and 17 are new claims. The specification supports new claims 16 and 17 and the amendment of claims 13 and 14 at, for example, page 5, lines 15-23 and page 7, line 3 to page 8, line 7.

The Office rejects the pending claims under 35 U.S.C. §§ 112, first paragraph, and 103. Before addressing these rejections, Applicants address the Office's request for certified copies of the Japanese priority applications.

#### **Priority Documents**

According to the Office, Applicants have not filed certified copies of priority documents JP 2004-021808 and JP2003-282691 with the Office or English translations of these priority documents. Office Action at 2. Applicants refer the Office to Applicants' Letter Requesting Acknowledgement of Receipt of Priority Document dated May 14, 2007. In the Letter, Applicants noted that the Form PCT/IB/304 indicated that the priority documents were submitted to the international bureau, thus satisfying the Office's requirements. For the Office's convenience, however, Applicants attach to this Amendment the certified copies of JP 2004-021808 and JP2003-282691 and their English translations as available on the European Patent Office's web site. Applicants

thus request that the Office acknowledge receipt of these priority documents in its next communication.

Written Description and Enablement

The Office rejects claims 10, 13, and 14 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Office Action at 3. According to the Office, the specification does not provide adequate written description support for accelerating salivation associated with Sjögren's syndrome and a prophylactic and/or treating effect of xerostomia associated with Sjögren's syndrome. *Id.* The Office contends that Applicants simply state in claims 13 and 14 that the invention can be used to treat patients with Sjögren's syndrome without explaining the specific mechanism of action or providing the results of their findings. *Id.* at 4. Applicants traverse with respect to claims 13 and 14, which are still pending.

Based upon the disclosures in the specification, one of ordinary skill in the art clearly would conclude that Applicants were in possession of the invention of claims 13 and 14. Claim 13 recites "treatment of xerostomia accompanying Sjögren's syndrome" and not "accelerating salivation associated with Sjögren's syndrome" as the Office implies. Claim 14 likewise recites "xerostomia accompanying Sjögren's syndrome." The specification provides ample written description support for the treatment of xerostomia accompanying Sjögren's syndrome. The "results of findings" that the Office requests are provided at pages 20-25 in Experiments 3 and 4. Both of these experiments describe studies done in patients with Sjögren's syndrome, showing that administration of 2-(4-chlorobenzoylamino)-3-(2-quinolon-4-yl)propionic acid significantly improved symptoms of xerostomia and significantly increased the amount of saliva produced. Because the specification demonstrates that Applicants were in

possession of the invention of claims 13 and 14, Applicants request that the Office withdraw this rejection.

Claims 10-15 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled. Office Action at 5. The Office contends that the specification does not enable a method of preventing xerostomia. *Id.* Applicants address this rejection with respect to claims 13 and 14, which are still pending. Solely in the interests of advancing prosecution and without acquiescing in the rejection, Applicants have amended claim 13 to remove the recitation of prophylaxis. New claims 16 and 17 likewise do not recite prophylaxis. Because Applicants' amendments render the Office's rejection moot, Applicants request that this rejection be withdrawn.

#### Obviousness

The Office rejects claims 10-15 under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent 5,476,858 ("Yamasaki") and Loguercio et al. (*Digestion* 36:91-95 (1987); "Loguercio"). Office Action at 8. Yamasaki allegedly discloses the use of the compound of the invention for treating diseases associated with a decrease in somatostatin. *Id.* Acknowledging that Yamasaki does not teach the ability of the compound to accelerate salivation, the Office turns to Loguercio for allegedly teaching that administering "a somatostatin, in this case pentagastrin, increases salivary secretion progressively." *Id.* The Office contends that one of ordinary skill in the art would have a reasonable expectation of success because Yamasaki allegedly teaches that the compound of the invention increases somatostatin while Loguercio allegedly teaches that somatostatin in turn increases salivation. Based on this rationale, the Office then suggest that one of ordinary skill in the art would conclude that a compound

that is known to increase somatostatin would further lead to accelerated salivation. Applicants traverse with respect to claims 13 and 14, which are still pending.

The Office's reading of Loguercio is incorrect. This reference does not teach that pentagastrin is a type of somatostatin. Rather, Loguercio discusses pentagastrin and somatostatin as two different compounds, each with different effects. Moreover, Loguercio does not teach that administering somatostatin resulted in increased salivation. Indeed, Loguercio teaches the opposite. Specifically, Loguercio reports that administration of *pentagastrin*, not somatostatin, resulted in increased salivation. When somatostatin was later given, somatostatin reversed the effect of pentagastrin on saliva production. In other words, treatment with somatostatin blocked the increase in saliva production so that saliva levels returned to pre-pentagastrin treatment levels. See Loguercio at page 92, right column; page 94, left column. Thus, clearly, Loguercio teaches that somatostatin has *negative* effects on increasing saliva production.

Given Loguercio's teaching that somatostatin almost completely inhibits acceleration of salivation, one of ordinary skill in the art would not arrive at the claimed invention when combining Loguercio with Yamasaki. Instead, Loguercio would discourage one of ordinary skill in the art from using the compounds in Yamasaki to accelerate salivation because those compounds lead to an increase in somatostatin, which as Loguercio teaches, negatively affects acceleration of salivation. Applicants therefore request that the Office withdraw this obviousness rejection.

### Conclusions

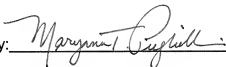
In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of claims 13, 14, 16, and 17.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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By:  \_\_\_\_\_

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